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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/668,314	09/22/2000	Mark Gurney	28341/6280NCP	1321

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EXAMINER

TURNER, SHARON L

ART UNIT PAPER NUMBER

1647

DATE MAILED: 01/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/668,314

Applicant(s)

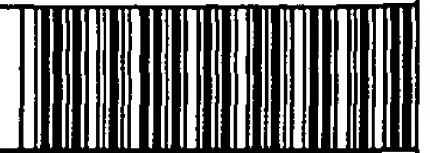
Gurney

Examiner

Sharon L. Turner, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 5-24-01

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-77 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1-77 are subject to restriction and/or election requirements.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s) _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____

20) ☒ Other: *Notice to Comply with Sequence Rules*

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☒ 7. Other: *The specification discloses and claims noncompliant sequences and sequences which are not referenced by Seq. ID. NO.*

Applicant Must Provide:

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

PatentIn Software Program Support

Technical Assistance.....703-287-0200

To Purchase PatentIn Software.....703-306-2600

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR REPLY

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1. It is noted that claim 64 is missing. The claims have been renumbered and dependencies changed accordingly. Claims 1-77 are pending.

Sequence Compliance

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

Applicant is given ONE MONTH from the mailing date of this communication within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

In particular, the claims do not comply with 37 CFR § 1.822(o) which states that “[a] sequence that is made up of one or more noncontiguous segments of a larger sequence or segments from different sequences shall be presented as a separate sequence”. Applicant needs to provide a substitute computer readable form (CRF) copy of a "Sequence Listing" which

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includes all of the sequences recited in the claims and specification of the instant application which are encompassed by these rules, a substitute paper copy of that "Sequence Listing", an amendment directing the entry of that paper copy into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. §§ 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d). The instant specification and/or claims will also need to be amended so that they comply with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. Specifically it is noted that the sequence which lacks residues 469-492 of SEQ ID NO:2 is non-contiguous and thus does not comply. Claim 62 contains sequences not referenced by SEQ ID NO. For rules interpretation Applicant may call (703) 308-1123. See M.P.E.P. 2422.04.

Improper Markush

3. Prior to setting forth the restriction requirement, it is pointed out that applicants have presented instant claims in improper Markush format, see Ex parte Markush, 1925 C.D. 126, In re Weber, 198 USPQ 334 and MPEP 803.02 and 806.04. The claims are improperly set forth as the claims encompassing multiple polynucleic acids, amino acids and methods of use which fail to share the characteristics of a genus, i.e., a common utility and a substantial structural feature essential to the disclosed utility. Alternatively, the claims define multiple structurally distinct compounds capable of different use, with different modes of operation, different function and different effects. A reference against one of the claimed components or methods would not be a

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reference against the other. Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because the claims define inventions which are not proper species.

Election/Restriction

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-14, drawn to polynucleotides, classified in class 536, subclass 23.1.
 - II. Claims 15-25, drawn to polypeptides, classified in class 530, subclass 300.
 - III. Claims 26-35, 48-49, and 51-52 drawn to a method of screening with contacting hu-Asp-1 or hu-Asp-1 encoded by hybridizing nucleic acids, classified in class 435, subclass 7.4.
 - IV. Claims 36 and 50 drawn to a method of screening further comprising treating Alzheimer's Disease, classified for example in class 424, subclass 130.1.
 - V. Claims 37-46, drawn to a method of screening with transfected host cells, classified in class 435, subclass 69.1.
 - VI. Claim 47 drawn to a method of screening with transfected host cells further comprising treating Alzheimer's Disease, classified in class 424, subclass 178.1.
 - VII. Claims 53-67, and 70 drawn to a method for assaying hu-Asp 1 α -secretase activity, classified in class 530, subclass 300.
 - VIII. Claim 68 drawn to a method of assaying further comprising treatment of Alzheimer's Disease, classified in class 514, subclass 2.

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- IX. Claim 69, drawn to a Asp1 protease substrate, classified in class 530, subclass 300.
 - X. Claims 71-74, drawn to a method of assaying Asp-1 proteolytic activity, classified in class 435, subclass 68.1.
 - XI. Claim 75, drawn to a composition that modulates APP processing, classified for example in class 536, subclass 23.1.
 - XII. Claim 76, drawn to a composition that modulates APP processing, classified for example in class 530, subclass 350.
 - XIII. Claim 77, drawn to a composition that modulates APP processing, classified for example in class 424, subclass 78.08.
5. The inventions are distinct, each from the other because of the following reasons:
6. Furthermore, in addition to the election of one of the above XIII groups, further restriction is required under 35 U.S.C. 121 as set forth below to delineate the molecular embodiment to which the claims will be restricted in accordance with the elected group:
- A) A single designated nucleic acid/polypeptide composition from the group of nucleic acids encoding or the polypeptides of 1) residues 1-469 of SEQ ID NO:2, 2) residues 492-518 of SEQ ID NO:2, 3) residues 63-469 of SEQ ID NO:2 and 4) residues 63-518 of SEQ ID NO:2.
 - B) A single determining step of 1) α -secretase processing/activity, 2) β -secretase processing/activity, 3) production of amyloid beta peptide, 4) production of amyloid alpha peptide.

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In order to be fully responsive applicant is required to elect a single Group from Groups I-XIII and a single embodiment from each of Groups A and B as set forth above.

7. The inventions are distinct, each from the other because of the following reasons:

8. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because the products indicated as A-B constitute patentably distinct inventions for the following reasons. Each of the polynucleotides, polypeptides and processed compounds has unique structural and functional features which require a unique search of the prior art. The inventions indicated as A-B differ in structure and function as they are composed of divergent nucleic and amino acids and are differentially able to hybridize bind and cleave. A reference to one element would not constitute a reference to another. In addition, searching all of the molecules in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because the indicated searches are not co-extensive.

9. Groups I, II, IX, XI, XII and XIII are related as products. Each product is distinct from the other due to their distinct structures, i.e., nucleic acids, amino acids, antibodies, organic and inorganic molecules. It is noted that the product is undefined in Groups XI-XIII.

10. Groups III-VIII and X are related as processes. Each process is distinct from the other due to their different steps, different reagents, and different functional outcomes.

11. Inventions I-II, IX and inventions III-VIII, X are related as products and processes of use.

The inventions can be shown to be distinct if either or both of the following can be shown: (1)

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the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case (1) the processes for using the products can be practiced with alternative nucleic acids, peptides, antibodies and inorganic molecules and (2) the products can be used in alternative methods of making polypeptides, in binding assays, competition assays, purification assays and in alternative methods of treatment.

12. Because these inventions are distinct for the reasons given above and the search required for any of the Groups is not required for any other Group, restriction for examination purposes as indicated is proper.

13. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

14. Claims 26, 37, 48, 53 and 69 are generic to a plurality of disclosed patentably distinct species comprising APP substrates including 1) APP, 2) APP with carboxy terminal di-lysine 3) APP Swedish mutation 4) LVFFAEDF, 5) KLVFFAED and 6) GLALALEP. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

16. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.
December 31, 2001

CHRISTINE J. SAOUD
PRIMARY EXAMINER

Christine J. Saoud